UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GOVERNMENT EMPLOYEES HEALTH ASSOCIATION, on behalf of itself and all other similarly situated,

Plaintiff,

v.

ACTELION PHARMACEUTICALS LTD., *et al.*,

Defendants.

[redacted]

HEARING REQUESTED

Civil Case No.: 18-cv-3560-GLR

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF TODD CLARK AND DAISY RIVERA-MUZZIO

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Rules

Defendants' (collectively, "Actelion's") motion to exclude the opinions and testimony of Daisy Rivera-Muzzio and Todd Clark should be denied. Actelion's chief complaint is that Ms. Muzzio and Mr. Clark's opinions are "directly contradicted by undisputed record evidence."[1] Under established precedent, however, an antitrust plaintiff is tasked with demonstrating what would have occurred *but for* the alleged unlawful conduct.[2] The law explicitly *allows* for the removal of the anticompetitive conduct, which *necessarily* entails analyzing events without that conduct. That is exactly what Ms. Muzzio and Mr. Clark do.

The anticompetitive conduct in this case is Actelion's scheme to delay market entry of lower-priced generic versions of its best-selling drug, Tracleer. Generic manufacturers must acquire samples of the brand product to conduct bioequivalence ("BE") testing—a prerequisite to filing an Abbreviated New Drug Application ("ANDA") to market a generic product. Actelion contractually prevented all distributors and pharmacies from selling samples to generic manufacturers and denied generic manufacturers' direct requests to Actelion to purchase Tracleer. Actelion falsely contended that the Tracleer Risk Evaluation and Mitigation Strategy ("REMS") prevented it from selling samples to the generics and at other times claimed that it needed a letter from FDA approving the generics' BE protocols. But this was just a pretext. Actelion's internal documents confirm that its true objective was to delay the entry of lower-priced generics. *See generally* GEHA's Summ. J. Opp. § IV.B.2. The delay in generic entry harmed patients and payers such as GEHA, who paid inflated prices for years longer than they should have.

[1] Defs.' Memorandum in Support, ECF No. 289-1 ("Br.") 2.

[2] *See e.g.*, *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 259, 263 (1946) (referring to proof of plaintiff's experience "in the absence of" the restraints or "if the restraints had not been imposed").

At trial, Ms. Muzzio and Mr. Clark's expert testimony will demonstrate to the jury—supported by their experience and the record evidence—how events would have unfolded without the anticompetitive samples blockade. To make this showing, Ms. Muzzio and Mr. Clark opine on: (1) where generics would purchase samples, and how long it would take to acquire the samples, develop the generic, and prepare an ANDA for filing (Ms. Muzzio); and (2) the timing of Food and Drug Administration ("FDA") approval of ANDAs and market entry by manufacturers of generic Tracleer (Mr. Clark). Together Ms. Muzzio and Mr. Clark have more than seventy years of experience in the pharmaceutical industry, working for brand and generic companies on the very issues on which they opine. In removing the anticompetitive conduct, neither relies on speculation—nor does either expert "assum[e] that in the but-for world there would be no REMS restrictions."[3] Rather, their analysis is anchored in the factual record and their own experience with REMS and non-REMS products, including purchasing brand samples, developing generic products, filing generic drug applications, and obtaining approval for the same.

Actelion's other complaint, that Mr. Clark did not disclose his opinion that the "Tracleer REMS did not prevent Actelion from providing samples,"[4] is belied by his reports and his deposition testimony. The opinion was properly disclosed under Fed. R. Civ. P. 26(a)(2)(c). Actelion's motion should be denied.

I. BACKGROUND

A. Summary and Purpose of Ms. Muzzio's Opinions and Analysis.

Actelion does not challenge Ms. Muzzio's qualifications. Ms. Muzzio has over forty years of experience in the pharmaceutical industry in all major operational areas spanning development

[3] Br. 17.

[4] *Id.* at 1.

and manufacturing operations for both brand and generic pharmaceutical companies, including Sterling Pharmaceuticals, Schein Pharmaceutical, Warner Lambert, and Pfizer Pharmaceuticals.[5] She has led pre-formulation and formulation activities for the development of generic pharmaceuticals, participated in the preparation and submission of ANDAs for FDA approval,[6] identified and procured brand samples—including for REMS and non-REMS brand products for BE testing—and authorized hundreds of purchase orders to acquire pharmaceutical products for testing purposes.[7]

Relying on this experience, Ms. Muzzio reviewed the record evidence in this case, including, *inter alia*, the characteristics of Tracleer as well as documents and deposition testimony. Based on the foregoing, she opines that if Actelion had not blocked generic companies' access to samples of Tracleer, five generic manufacturers, or reasonable companies in their positions, would have done what generic manufacturers typically do: purchased samples through the normal channels (*i.e.*, distributors and specialty pharmacies) pursuant to their federal and state licensure. She further opines that this procurement would take three months.[8] Ms. Muzzio's opinion is consistent with her decades of experience purchasing samples of REMS and non-REMS drugs through these normal channels, and is also conservative with respect to the timeframe because procurement of Reference Listed Drug ("RLD") samples typically takes "a few weeks to three

[5] *See* Ex. 1, 12/22/2022 Expert Rep. of Daisy Rivera-Muzzio ("Muzzio Rep.") ¶¶ 10–15.

[6] *See id.* ¶¶ 17, 24, 28–29, 31, 85–86, 92, 94–139 & Ex. B ("Materials Relied On"); *see also* Ex. 2, 8/9/2023 Dep. of Daisy Rivera-Muzzio ("Muzzio Tr.") at 22:7–12 (depositions and materials relied on).

[7] *See* Ex. 1, Muzzio Rep. ¶¶ 7-16, 24, 28-31, 85-86, 92, 94; Ex. 2, Muzzio Tr. at 42:20–25 ("I have significant experience procuring samples of branded product for research purposes covered by REMS, non-REMS, controlled substances."); *id.* 195:7–197:6. While Actelion has not challenged Ms. Muzzio's qualifications, her experience is a cornerstone of her opinions.

[8] *See* Ex. 1, Muzzio Rep. ¶¶ 6, 23 & 140; s*ee also id.* ¶ 6 (summarizing opinions).

months."[9] Ms. Muzzio nonetheless conservatively applied a three-month sample procurement timeframe to all of her timelines.[10]

Ms. Muzzio also applied her experience to her review of the factual record to determine how long it would take each of the five generic manufacturers to complete product development and file an ANDA. Based on her analysis of documents and testimony associated with each, Ms. Muzzio opines that the generic manufacturers, or reasonable companies in their position, would have completed product development requirements and been ready to file their ANDAs as follows:

- [redacted]: within 21 months of their first efforts to purchase samples;
- [redacted] within 15 months of its first efforts to purchase samples;
- [redacted]: within 27 months of its first efforts to purchase samples; and
- [redacted] by August 31, 2011.[11]

Ms. Muzzio's product development timelines are likewise conservative. In her experience, some pre-formulation work can be completed prior to receiving samples. But Ms. Muzzio conservatively assumed for her analysis that pre-formulation work would have begun only after samples were procured.[12]

[9] *Id.* ¶ 31. "[T]he usual time to complete the routine administrative process of issuing a purchase order, coordinating the acquisition of samples, and receiving the samples of any product is between a few weeks and three months." *Id*. ¶ 27; *see also* Ex. 2, Muzzio Tr., at 19:2–5 ("these companies could have procured samples in a matter of a couple of weeks to—up to three months, just to be very conservative"); *id*. at 23:4–8 ("manufacturers followed a very routine process to get samples . . . I was very conservative.").

[10] *See* Ex. 1, Muzzio Rep. ¶ 31 n.12.

[11] *See id.* ¶¶ 23 & 140; s*ee also id.* ¶ 6 (summarizing opinions).

[12] *See id.* ¶ 35.

B. Summary and Purpose of Mr. Clark's Opinions and Analysis.

Utilizing Ms. Muzzio's opinions regarding the timing of samples procurement and ANDA filings as inputs, Mr. Clark opines on how long it would take those same generic manufacturers to satisfy FDA approval requirements after filing their ANDAs.[13] Like Ms. Muzzio, Mr. Clark has decades of experience in the pharmaceutical industry. He is currently President of VOI Consulting. Over the past thirty years, numerous brand and generic drug companies have retained him to provide guidance on regulatory and strategic planning and execution.[14] Mr. Clark advises these companies on drug development, clinical trial design, regulatory and REMS compliance, launch forecasting, and competitive intelligence.[15] Among the myriad drugs that Mr. Clark has worked on, at least thirteen drugs have been covered by REMS/RiskMAPs.[16] Mr. Clark also conducted a meticulous review of the evidence in this case. His robust reports discuss: the market incentives driving generic companies, the availability of generic Tracleer as early as 2012 in other highly-regulated countries, the large number of generics ultimately approved in the U.S., documents including the Tracleer REMS and the generic companies' actual ANDAs, fact witness testimony, statements made by Congress, the FDA, and other public institutions, and empirical analysis of data regarding generic drug approval times in the relevant timeframe.[17]

Mr. Clark's opinion regarding when generic companies would have launched their product will inform the jury of how events would have unfolded absent Actelion's misconduct. Those entry dates matter, because patients and payers such as GEHA overpaid during the time period when

[13] Ex. 3, 12/22/2022 Expert Rep. of Todd Clark ("Clark Rep.") ¶¶ 95–228.

[14] *Id.* ¶ 3.

[15] *Id.* at Ex. 1.

[16] *Id.* ¶ 5.

[17] *Id.*

generics were unavailable; it will therefore be the jury's task to determine how long of a delay period Actelion caused. Mr. Clark's testimony will assist jurors with that task.

Relatedly, Mr. Clark opines on the timeline for approval of the shared Risk Evaluation and Mitigation Strategies program ("SREMS").[18] Generic Tracleer applicants were required to jointly develop and agree upon—with Actelion and each other—a single SREMS program to cover all bosentan drugs (brand and generic). Approval of the SREMS is a prerequisite to ANDA approval. In his opinion, Mr. Clark concluded that absent Actelion's misconduct, the SREMS process would have been shortened "by at least several months, and potentially up to a year or more" were it not for Actelion's challenged conduct.[19] He reaches this opinion based on documents and testimony from three different generic manufacturers *and* the neutral SREMS manager.[20] Actelion disputes this opinion. Regardless of who is correct, Mr. Clark opines that generics would have launched earlier even if the SREMS process took the same duration as in the actual world.[21] Accordingly, at trial, Mr. Clark will provide an opinion both as to when generics would have launched if the jury finds the SREMS process would have been shortened; and when they would have launched if the jury finds the SREMS process would have taken the same amount of time.[22]

II. LEGAL STANDARD

To testify at trial as an expert, the Federal Rules of Evidence require a witness to be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Testimony

[18] *Id.* ¶¶ 276–82.

[19] *Id.* ¶ 281.

[20] *Id.* ¶ 280.

[21] As Mr. Clark notes in his report, another GEHA expert, former Acting Director of the Office of Generic Drugs at FDA, Dr. Keith Webber, separately opines that the Tracleer SREMS process would have taken no longer than it did in the actual world. *Id.* ¶¶ 277, 287.

[22] *Id.* ¶¶ 287-289.

is admissible if it (a) "will help the trier of fact to understand the evidence or to determine a fact in issue," (b) "is based on sufficient facts or data," (c) "is the product of reliable principles and methods," and (d) the expert has reliably applied "the principles and methods to the facts of the case."[23] The Supreme Court strongly disfavors exclusion, preferring instead "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof."[24] "[R]ejection of expert testimony is the exception rather than the rule."[25]

Rule 702's requirement "that the evidence or testimony '[help] the trier of fact to understand the evidence or to determine a fact in issue'" goes primarily to relevance.[26] It is for the jury "to evaluate the reliability of the underlying data, assumptions, and conclusions."[27]

III. ARGUMENT

At trial, the relevant causation question for the jury is: if Actelion had not prevented generic companies from purchasing the Tracleer samples they needed to develop competing products, would those generics (or reasonable companies in their positions) have launched their generic products earlier than they did in the actual world? If so, when? Ms. Muzzio and Mr. Clark's reliable and relevant opinions will help the trier of fact address these questions. They are therefore admissible.[28]

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[23] *Id*.

[24] *Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 596 (1993).

[25] Fed. R. Evid. 702, Advisory Committee's Notes to 2000 Amendment.

[26] *Daubert.*, 509 U.S. at 591 (quoting Fed. R. Evid. 702).

[27] *In re Urethane Antitrust Litig*., 768 F.3d 1245, 1263 (10th Cir. 2014); *see also Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806 (7th Cir. 2013) ("Rule 702[] . . . does not ordinarily extend to the reliability of the conclusions [an expert's] methods produce—that is, whether the conclusions are unimpeachable." (quoting *Stollings v. Ryobi Techs., Inc*., 725 F.3d 753, 765 (7th Cir. 2013))); *In re Sulfuric Acid Antitrust Litig*., 743 F. Supp. 2d 827, 866 (N.D. Ill. 2010) ("The credibility and persuasiveness of Plaintiffs' expert witnesses are issues best left to a factfinder.").

[28] *See* Fed. R. Evid. 702.

A. Ms. Muzzio's opinions are admissible under Rule 702 and satisfy *Daubert*.

Actelion seeks to exclude two of Ms. Muzzio's opinions: (a) the time it would take from each generic's first efforts to procure Tracleer samples to actually procuring them in the but-for-world; and (b) the time it would take from each generic's procurement of samples to submit an application for FDA approval in the but-for-world.[29] Actelion argues that these opinions are (1) unreliable because they are "directly contradicted by undisputed record evidence," and "ignore[] the dictates of the Tracleer REMS,"[30] and (2) will confuse and be unhelpful to the jury because they "contradict[] factual reality," and "actual [real event] timelines . . . can be freely analyzed by the jury."[31] Actelion's arguments are wrong, factually and legally. They do not support exclusion.

1. Ms. Muzzio's opinions are reliable, relevant, fit the facts, and are consistent with the law.

Ms. Muzzio's opinions properly address when and how events—from procuring Tracleer samples, through product development, to ANDA submission—would have occurred without Actelion's anticompetitive conduct. Her opinions are informed by and consistent with her decades of experience *and* her assessment of the relevant contemporaneous facts and regulations. Her opinions are thus relevant and reliable under *Daubert* and Rule 702, central to GEHA's causation burden under antitrust law, and will aid the jury with its causation assessment.

a. Under a but-for causation theory, Ms. Muzzio must testify how events would unfold *without* the anticompetitive conduct.

Actelion accuses Ms. Muzzio of improperly "assuming" how events would have unfolded absent unlawful actions by Actelion.[32] As discussed below, Ms. Muzzio "assumed" nothing. And

[29] Br. 2.

[30] *Id.* at 2, 8, 16, 17 & 21.

[31] *Id.* at 23, 24 & 25.

[32] *Id.* at 6-7, 21-23.

as an initial matter, Actelion is wrong on the law. Antitrust law requires, and Rule 702 permits an expert to proffer opinions based upon their experience and the factual record *from which the alleged anticompetitive conduct is removed*.[33] Courts recognize and accept that such an analysis necessarily involves describing events that did not occur in the actual world, which was tainted by the anticompetitive conduct.[34] In *In re Zetia (Ezetimibe)*, a pharmaceutical antitrust case alleging delayed generic entry, the court explained, "[b]oth parties understand that Plaintiffs must prove their case counterfactually."[35] The Court rejected defendants' *Daubert* argument that plaintiffs' expert's opinions should be excluded because they differed from actual events.[36]

Ms. Muzzio's opinions are relevant under this established antitrust framework. Her testimony addresses a question that the jury must determine: had Actelion not erected its anticompetitive samples blockade, how long would it have taken the generic companies for whom she provides timelines, or reasonable generic companies in their positions, to purchase samples, complete formulation and development work, and to prepare and submit ANDAs to FDA? To evaluate this question, the jury must understand how actual events would have occurred *without* Actelion contractually preventing all distributors and pharmacies from selling Tracleer to generic manufacturers, and *without* Actelion's pretextual use of the REMS for Tracleer to deny generic

[33] *See, e.g.*, *Kleen Prods. LLC v. Int'l Paper Co*., 831 F.3d 919, 927 (7th Cir. 2016) (explaining that a "plaintiff could satisfy its burden" to establish antitrust injury through "an expert construction of a hypothetical market free of any anticompetitive restraint"); *Blades v. Monsanto Co.*, 400 F.3d 562, 569 (8th Cir. 2005) (explaining that hypothetical market must be "free of the restraints and conduct alleged to be anticompetitive" (quoting *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir. 2000))); *Apotex, Inc. v. Cephalon, Inc*., 321 F.R.D. 220, 236 (E.D. Pa. 2017) ("When recreating a but-for world to establish antitrust damages, a plaintiff must create a world 'characterized by the absence of the . . . challenged practices.'") (citation omitted)).

[34] *See id*.

[35] *See In re Zetia (Ezetimibe) Antitrust Litig.* 2022 WL 4362166, at *11 (E.D. Va. Aug. 15, 2022) ("*Zetia I*").

[36] *Id*. at *7-8 (citation omitted). Actelion relies on this same rejected argument.

manufacturers' direct requests to purchase Tracleer. It took generic companies years between their first efforts to purchase samples and their ultimate ability to submit ANDAs to FDA—all due to Actelion's conduct delaying their ability to procure brand Tracleer. The jury must—and, aided by Ms. Muzzio, will—determine how long that process would have taken *absent* Actelion's samples blockade. Because her testimony will inform the jury's assessment of this central causation question, it is relevant.

b. Ms. Muzzio's opinions are grounded in her experience and consistent with the facts and law.

"In offering their opinion, experts may consider disputed facts."[37] "A court thus 'should not disregard plaintiff's version of disputed facts when considering reliability and fit of an expert opinion under *Daubert*.' Expert testimony is admissible when experts 'opine only on what the [analysis] should be *if* the jury separately finds the facts [they] assume[] to be true.'"[38] Reliance on a disputed fact does not impact the expert's reliability.[39] The Court's gatekeeper function does not require determining "that the expert testimony . . . . is irrefutable or certainly correct."[40]

First, Ms. Muzzio did not ignore record facts or make up facts, as Actelion argues.[41] "[U]nder Rule 702, an experiential expert witness [must] explain how [his or her] experience leads

[37] *In re Zetia (Ezetimibe)*, 2022 WL 3337796, at *6 (E.D. Va. Aug. 3, 2022) ("*Zetia II*") (citations omitted).

[38] *Id.* at *7 (emphasis added) (citations omitted).

[39] *Bresler v. Wilmington Tr. Co.*, 855 F.3d 178, 195–96 (4th Cir. 2017).

[40] *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162, n.14 (4th Cir. 2012) (citations omitted).

[41] *See* Br. 6, 7, 21 & 23 (arguing that Ms. Muzzio cannot "assume" that Tracleer would have been available through "normal distribution channels" in the absence of Actelion's alleged anticompetitive conduct). One example of record support for Ms. Muzzio's analysis is a letter from generic manufacturer Roxane's counsel to Actelion referring to the generic's practice of "normally [purchasing samples] in the ordinary course of business[] from pharmaceutical wholesalers." Ex. 4, 6/6/2011 Ltr. to Actelion at -887.

to the conclusion reached, why [his or her] experience is a sufficient basis for the opinion, and how [his or her] experience is reliably applied to the facts."[42] Ms. Muzzio did so at length in her report and deposition, explaining how her analysis and opinions are grounded in her experience and supported by and consistent with the record.[43]

Ms. Muzzio's experience is directly on point. During her decades at brand and generic pharmaceutical companies, Ms. Muzzio and her team of scientists routinely sought and purchased REMS and non-REMS brand product samples for BE testing.[44] With respect to samples procurement in particular, as she testified during her deposition: "I didn't assume. It is my opinion, based on my decades of experience and the hundreds of times that I've purchased brand samples, that these companies could have procured samples in a matter of a couple of weeks to—up to three months, just to be very conservative."[45]

With respect to her opinions regarding the timing of ANDA filings, Ms. Muzzio summarized the extensive contemporaneous evidence that she reviewed while conducting her generic-by-generic analysis and developing timelines absent the samples blockade.[46] As her report demonstrates, Ms. Muzzio *did* consider actual development timelines and assessed the extensive impact of the challenged conduct at every stage, in reaching her intentionally conservative

[42] *Wood v. Credit One Bank*, 277 F. Supp. 3d 821, 855–56 (E.D. Va. 2017) (citation omitted).

[43] *See, e.g.*, Ex. 1, Muzzio Rep. ¶ 24, 85–87.

[44] *See supra*, n.7.

[45] Ex. 2, Muzzio Tr. at 18:24–19:5. Nor are timeframes used by Ms. Muzzio for the five generic companies' earliest efforts to purchase samples speculative. She cites to deposition testimony and internal documents produced by generic companies in this case. *See, e.g.,* Ex. 1 Muzzio Rep. ¶¶ 65, 71, 77, 81, 96. Actelion simply ignores that its blockade extended to its actions contractually barring manufacturers from purchasing samples from distributors.

[46] *See*, *e.g.*, Ex. 1, Muzzio Rep. ¶¶ 7–16, 24, 28–29, 31, 85–94 & nn.53–64; *see, e.g.*, Ex. 2, Muzzio Tr. at 22:7–12; 38:14–20; 42:20–25 (discussing experience and materials reviewed).

opinions about the length of each generics' development timeline absent the alleged antitrust violation.[47] She explained in her report:

> 85. . . . I identified FDA regulatory guidance documents applicable to the relevant timeframe. I also identified specific sections of the generic companies' ANDAs for generic Tracleer, as filed with the FDA, to review the ingredients, techniques, equipment, and project planning tools that companies used in developing their ANDAs for generic Tracleer, as well as certain internal communications concerning development efforts.
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> 86. . . . I first conducted a review of all available evidence regarding the characteristics of the Tracleer drug product to assess the relative ease of formulating a generic version . . . reviewed formulation and development efforts undertaken by the generic companies covered in my opinion (Mylan, Zydus, Watson/Actavis/Teva, Par**,** and Roxane/Hikma) . . . reviewed the relevant portions of each company's generic Tracleer ANDA files, including detailed Product Development Reports submitted to the FDA, which summarize in detail each company's formulation and development process. . . [and] reviewed various other documents submitted to the FDA, such as batch records, certificates of analysis, stability reports, validation reports, and clinical study reports, to learn additional information about each company's formulation and development timeline.[48]

Her opinions are properly grounded in her experience and her review of the factual record.

Second, Ms. Muzzio's opinions do not contradict the law. Actelion argues that the REMS for Tracleer, not Actelion's unlawful acts, prevented the generics from obtaining samples.[49] As

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[47] *See, e.g.*, Ex. 1, Muzzio Rep. ¶ 24. Ms. Muzzio explained that her opinions are:

> . . . based on my experience with product samples procurement and the product development process, my review of the characteristics of Tracleer specifically, and my review of the timeframes in which each of these companies is first known to have started seeking to purchase samples of RLD Tracleer from Actelion or a distributor . . . [I determined]: (a) the length of time from the date samples were requested to the date the would have been received had Actelion allowed the sale of samples or allowed its distributors to sell samples to generic manufacturers, and (b) the length of time for the various stages of development of a generic pharmaceutical product as described below, in light of the information available regarding each generic manufacturers actual formulation and development efforts and the regulatory requirements in place at the relevant times, but without the samples-related delays that they experienced.

[48] *Id.* ¶¶ 85–87.

[49] Br. 4, 21–23.

discussed in Plaintiff's Opposition to Defendants' Motion for Summary Judgment, filed contemporaneously herewith, there is no textual basis in either the REMS or FDA regulations for Actelion's bald arguments. Actelion's view is also contradicted by FDA's clear statement that such blocking efforts *are* an abuse of the REMS system.[50]

Ms. Muzzio's opinions are also substantiated by the record facts, including Actelion's provision of brand samples to researchers while it blocked sample sales to generic manufacturers, and the short timeframe within which Actelion filled generic manufacturers' samples orders after years of delay. Indeed, Actelion provided brand samples to researchers throughout the period that it blocked the generic's efforts to procure samples, including without requiring compliance with the Tracleer REMS.[51] In contrast, with the generics, even when Actelion received the assurances it purported to need, it delayed the provision of samples.[52] And when Actelion eventually sold its samples to generic manufacturers, those orders were fulfilled within shorter timeframes—just as Ms. Muzzio opined they could have been.[53]

Third, Actelion's additional arguments are quintessential red herrings. Actelion argues that Ms. Muzzio did not review or analyze (a) how long it actually took any company to submit an ANDA, (b) when any of the companies were able to obtain samples of Tracleer for research in the actual world, (c) whether any of the companies she reviewed actually had their ANDA approved,

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[50] Actelion was featured on an FDA list among the top offenders that had thwarted competitors from developing generic versions of multiple products, including Tracleer, by withholding samples. *See* Ex. 5, 5/17/2018 FDA Statement; Ex. 6, FDA Reference Listed Drug (RLD) Access Inquiries.

[51] Ex. 7, 9/27/2022 Dep. of Ryan Harris at 87:22-88:8.

[52] Ex. 8, 5/30/2013 Ltr. to Apotex.

[53] Ex. 1, Muzzio Rep. ¶ 31 n.12; *see* Ex. 2, Muzzio Tr. at 193:7–194:23 (". . . [redacted] did it on May 12 and the samples were ready for pickup on June 2; and in the case of [redacted] . . . the purchase order was issued on March 21st and the samples were ready for pickup on March 31st, so couple of weeks. That is exactly the time frame for requesting samples and receiving samples.").

or (d) whether and when any of the companies actually brought a generic form of Tracleer to market.[54] As discussed, *supra* 9-10, (a) and (b) are infected by Actelion's anticompetitive acts. Regardless, contrary to Actelion's claims, Ms. Muzzio explained in her report and deposition that she *did* carefully consider actual generic development and acquisition timelines.[55] Also contrary to Actelion's assertions, Ms. Muzzio reviewed and considered when companies actually submitted their ANDAs. Post-ANDA filing events—(c) and (d)—are beyond the scope of her assignment. GEHA relies on other experts to address these issues.[56] For the same reasons, the five generic manufacturers' ultimate approval dates are not within the scope of Ms. Muzzio's opinions. These issues on which she did not opine cannot be subject to exclusion.

Without citing any authority, Actelion also takes issue with Ms. Muzzio's analysis of five generic manufacturers whose purchases of brand samples were blocked by Actelion rather than some greater number of additional generic manufacturers.[57] Actelion does not explain why focusing her analysis on these delayed generic companies is a ground for exclusion. It is not. Rather, it is a conservative approach. Ms. Muzzio also explained in her deposition: "based on the

[54] Br. 8; *see also* 24–25.

[55] *See, supra* n.46; Ex. 1, Muzzio Rep. ¶ 87 ("The timeline of actual formulation and development activities undertaken, while helpful to understand the capabilities and development approach for each generic company, was impacted by the inability to purchase samples of brand Tracleer. . . . the dates on which each company's development process was initiated, the time it took to complete certain steps, and the amount of time between certain steps, and even the order in which steps were performed, were significantly impacted by the years-long delays in procurement of U.S. RLD samples.").

[56] *See* Ex. 2, Muzzio Tr. at 10–21 (testifying that she understood GEHA's expert, Keith Webber, "was opining on whether the REMS affected the purchase of samples by the generics."). This is common and permissible. *See Concordia Pharms., Inc. v. Method Pharms, LLC*, 2016 WL 1464639, at *4 n.2 (W.D. Va. Apr. 13, 2016) ("an expert's 'data and testimony need not prove the plaintiff's case by themselves; they must merely constitute one piece of the puzzle that the plaintiffs endeavor to assemble before the jury.'").

[57] *See* Br. 7, 21.

specific information of each company. . . I feel very confident that any company in a similar situation or circumstances at each of the company, [sic] would have developed the product within the same/similar time frame."[58]

Actelion's cited cases are inapplicable. *Samuel* and *Sardis* are not antitrust cases and do not address expert testimony relevant to establishing a but-for causation theory nor any issue applicable to the facts and context before this Court.[59] And, unlike the facts in *Tyger*, Ms. Muzzio relied on her industry experience, and she analyzed relevant record facts. Her opinions are properly grounded in the factual record.[60] Accordingly, Actelion's arguments fail.

2. Ms. Muzzio's opinions will assist the jury.

Actelion claims that "[t]he date on which ANDA's for generic Tracleer were submitted to the FDA has little to no correlation with when any particular company was prepared to market their version of generic Tracleer,"[61] and that "when the first step in the approval process could have possibly taken place for certain companies in a fictitious world contradicts factual reality" and "is highly likely to confuse the jury."[62] These arguments are illogical and ignore the governing law.

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[58] Ex. 2, Muzzio Tr. 136:11–18. Actelion references Apotex in its brief but omits an important fact. *See* Br. 22–23. Notably, after Apotex spent years jumping through Actelion's pretextual hoops, Actelion admitted that its refusal to sell samples to Apotex "is not premised on the existence of the Tracleer REMS." Ex. 8, 5/30/2013 Ltr. to Apotex.

[59] Br. 21. *Samuel v. Ford Motor Co*., 112 F. Supp. 460 (D. Md. 2000) (involving product defect laws and addressing the reliability of an expert's scientific test related to car rollovers); *Sardis v. Overhead Door Corp*., 10 F.4th 268 (4th Cir. 2021) (involving products liability law and addressing, *inter alia*, the reliability of design defect and failure to warn expert testimony). For the same reasons, *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194 (4th Cir. 2001), involving expert opinions on the safety of a medical device, is not applicable. *See* Br. 9.

[60] *Tyger Const. Co. v. Pensacola Const. Co*., 29 F.3d 137 (4th Cir. 1994).

[61] Br. 25.

[62] *Id.* at 24–25.

First, as discussed herein, Actelion's argument that Ms. Muzzio's opinions should be excluded because "when the first step in the approval process" would have occurred in a but-for-world "contradicts factual reality"—is *directly contrary to antitrust law*. Antitrust law requires GEHA to demonstrate how events would have unfolded but for Actelion's alleged conduct.[63] And antitrust law explicitly allows for removing that alleged conduct so that GEHA can demonstrate how, "but for" Actelion's conduct, the generic manufacturers would have procured samples and filed their ANDAs earlier. Actelion misapplies the law. This is not a basis for exclusion.

Second, lay jurors are not familiar with the processes and timelines for procuring pharmaceutical samples, developing generic products, and filing ANDAs—and they cannot be expected to understand these processes and timelines (or how they were impacted by the unlawful conduct) without the aid of an expert. Ms. Muzzio analyzed the ways in which the generics' development timelines were infected at multiple stages by the delay in access to brand samples up to their ANDA submissions, and provided individualized opinions on the "but for" development timelines if the delays were excised.[64] The documented delays in the actual timelines are precisely why her opinions and individualized timelines are important and will aid the jury. At trial, Ms. Muzzio's expert testimony will enable the jury to understand how each of those processes and timelines would have unfolded without the taint of Actelion's misconduct.

It is difficult to understand how Actelion could credibly dispute the utility of Ms. Muzzio's testimony under these circumstances. Here, Ms. Muzzio's testimony is indisputably relevant to the causation issues in this case. Her opinions do not have a "greater potential to mislead than to

[63] *See e.g.*, *Bigelow*, 327 U.S. at 259, 263 (referring to proof of plaintiff's experience "in the absence of" the restraints or "if the restraints had not been imposed").

[64] *See*, *e.g.*, Ex. 1, Muzzio Rep. ¶¶ 86–92.

enlighten."[65] Just the opposite. Actelion cannot use *Daubert* to bar admissible opinions. "[T]he traditional and appropriate means" of challenging expert testimony are "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof."[66] The jury may assess the weight of this evidence at trial.[67]

Actelion's cited cases here provide no support to the contrary. In *Portsmouth Paving*, expert testimony was excluded as cumulative and because the jury could understand that costs increase the farther a contractor travels to a project, without expert testimony.[68] *Batzli* is not a pharmaceutical antitrust case and did not address expert testimony relevant to establishing a but-for causation theory.[69] Actelion's invitation to exclude Ms. Muzzio's opinions as a "side show" that will "muddle the analysis"[70] is cavalier and not grounds to exclude her well supported opinions.

B. Mr. Clark's opinions are admissible under Rule 702 and satisfy *Daubert*.

Mr. Clark, MS, MBA, has over thirty years of experience working in the pharmaceutical industry.[71] Currently the President of VOI Consulting, Mr. Clark holds a MS in Regulatory Science: Drug Development and Regulation from Johns Hopkins University and an MBA in Management Strategy, Marketing, and Finance from Northwestern University. Since 2003, Mr.

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[65] *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999).

[66] *Karn v. PTS of America, LLC*, 590 F. Supp. 3d 780, 801 (D. Md. 2022) (citing *Glass v. Anne Arundel Cty.*, 38 F. Supp. 3d 705, 714 (D. Md. 2014), *aff'd*, 716 F. App'x 179 (4th Cir. 2018)); *accord United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006), *overruled on other grounds*, *United States v. Foote*, 784 F.3d 931 (4th Cir. 2015).

[67] *See*, *e.g.*, *TFWS, Inc. v. Schaefer*, 325 F.3d 234, 240 (4th Cir. 2003) (whether an expert's calculations support his conclusion goes to the weight, not admissibility, of the evidence).

[68] *United States v. Portsmouth Paving Corp.*, 694 F.2d 312 (4th Cir. 1982).

[69] *Minnesota Lawyers Mut. Ins. Co. v. Batzli*, 2010 WL 670109 (E.D. Va. Feb. 19, 2010).

[70] Br. 25.

[71] Ex. 3, Clark Rep. ¶ 3.

Clark has taught courses on business, healthcare, and the pharmaceutical industry at Trinity College Dublin's MBA program, at Tulane University, and at Loyola University. He authors *PharmaHandbook—A Guide to the International Pharmaceutical Industry*, a single-source reference guide on pharmaceutical business and regulatory environments in 39 countries, and *Generic Handbook–A Guide to the US Generic Pharmaceutical Industry*, a comprehensive reference guide to the marketing, intellectual property, legal, regulatory, and competitive aspects of the generic drug sector in the United States.[72] Mr. Clark's decades of professional experience in the industry include regulatory work on numerous ANDA products, and at least thirteen drugs covered by REMS/RiskMAPs.[73]

Actelion seeks to exclude as unreliable Mr. Clark's opinions regarding (1) whether the Tracleer REMS prohibited the sale of Tracleer samples to generic companies; and (2) when FDA approval of generic versions of Tracleer—and particularly approval of the SREMS—would have occurred absent Actelion's samples blockade. As discussed in more detail below, Mr. Clark's professional experience is more than adequate to support each of these opinions. His analysis is rigorous, well-grounded in the record, and will be helpful to jurors. This Court should deny Actelion's motion to exclude Mr. Clark's opinions, as courts have uniformly done in other cases.[74]

1. Mr. Clark's opinion that the Tracleer REMS did not prohibit sample sales to generics is well supported.

Actelion falsely claims "[t]here is no meaningful analysis in Mr. Clark's reports in support of his opinion regarding the Tracleer REMS."[75] Mr. Clark's opinion that the REMS program did

[72] *Id.* ¶ 6, Ex. 1.

[73] *Id.* ¶ 5.

[74] *Zetia I*, 2022 WL 4362166, at *63–84; *In re Asacol Antitrust Litig.*, 323 F.R.D. 451, 467 (D. Mass. 2017).

[75] Br. 12.

not prohibit sale of samples to generic companies is supported by his analysis of the REMS documentation itself, deposition testimony of fact witnesses, contemporaneous documents produced in discovery by Actelion and non-party generics, as well as public statements of Congress, FDA, and the FTC, all of which unequivocally endorse that samples of REMS drugs be available for generic drug development.[76] Actelion relies on a patchwork of misleading partial quotations from Mr. Clark's deposition, but, when reviewed in context, they do not support Actelion's argument. For example, Mr. Clark testified that it was "not appropriate" to reference the Tracleer REMS in "*that paragraph*" of his report because it contained a discussion of the statute governing REMS generally.[77] But he also testified that he specifically reviewed the Tracleer REMS and supporting documents, and concluded it did not prohibit inter-company sales of brand Tracleer for testing purposes.[78] Indeed, he was able to specify from memory the date of the version of the Tracleer REMS he relied on.[79] He also reviewed everything cited in the reports of Actelion's experts Mr. Shimer and Dr. Nicholson for his rebuttal report, including everything they considered related to this issue.[80]

Mr. Clark repeatedly explained his method of analysis despite Actelion's counsel's urging that he apply a different one. Mr. Clark's "different concepts . . . of what analysis is" refers to defense counsel's insistence that review of relevant evidence must start *and end* with the four

[76] *See, e.g.*, Ex. 5, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition* (May 17, 2018) ("I want to be very clear: a path to securing samples of brand drugs for the purpose of generic drug development should always be available.").

[77] Ex. 9, 8/31/2023 Dep. of Todd Clark ("Clark Tr.") at 101:13–17.

[78] *Id.* at 107:7–23.

[79] *Id.* at 96:19–97:1.

[80] *Id.* at 108:19–22. *See also infra* nn.120 and 121, collecting Mr. Clark's supporting analysis.

corners of the Tracleer REMS program documents (which, as noted, Mr. Clark reviewed and concluded contained no prohibition on selling product to generic manufacturers for testing).[81] The laws and regulations regarding REMS, and statements by Congress, FDA, and FTC are all relevant to any analysis of whether sale of Tracleer samples to generic companies for testing purposes was permitted. Mr. Clark considered and relied on this information *in addition to* the Tracleer REMS itself, including communications with FDA regarding the Tracleer REMS and FDA policies regarding REMS generally.[82] Actelion's narrow view of what is relevant makes *Actelion's* analysis unreliable—not Mr. Clark's. To the extent Actelion disagrees, it will be free to cross-examine Mr. Clark at trial, but that disagreement does not render Mr. Clark's opinions unreliable.

2. Mr. Clark has more than adequate experience to opine on REMS requirements and generic approval timing.

Actelion's claim that Mr. Clark "has no real experience analyzing or applying REMS restrictions"[83] is typical of the mischaracterizations throughout its motion. In truth, Mr. Clark has decades of substantial, direct experience with REMS and its predecessor, RiskMAP[84] and has worked on multiple products covered by such programs.[85] For example, Mr. Clark performed a comprehensive strategic analysis to support the marketing of the drug Tysabri, one of the first products covered under a RiskMAP program.[86] Most relevant here, he advised on "what type of

[81] Ex. 9, Clark Tr. at 109:21–110:4.

[82] *Id.* at 103:12–22 ("I think laying the groundwork for how the FDA, the FTC, and others viewed this situation with Tracleer and with other brand drugs, subject to REMS, is relevant to the—to whether the Tracleer REMS program—to that specific aspect of whether it was violated or not, violated under the distribution terms."); *see generally id.* at 94–108.

[83] Br. 14.

[84] By comparison, Actelion's expert Professor Nicholson has no professional experience to support his opinions regarding the REMS program.

[85] Ex. 3, Clark Rep. ¶ 5; Ex. 9, Clark Tr. at 50:15-57:11.

[86] Ex. 9, Clark Tr. at 54:18-57:11.

distribution of Tysabri was permitted by the Tysabri RiskMAP."[87] As another example, he provided similar strategic support for the distribution of Aranesp, another RiskMAP/REMS product.[88] Mr. Clark established the REMS consulting program at Medicus, a pharmaceutical communications consulting firm, and when Congress passed the statute authorizing REMS, he advised pharmaceutical manufacturers on the process of transitioning from RiskMAP to REMS. To date, he has worked on at least thirteen drugs covered by REMS/RiskMAPs.[89] These years of specific industry experience qualify him to offer the REMS opinion Actelion seeks to exclude.

Similarly, Mr. Clark's experience qualifies him to opine on the timing of FDA approval absent Actelion's samples blockade. Contrary to Actelion's suggestion, when asked during deposition if he was an expert in "regulatory law," Mr. Clark testified, "I'm not a lawyer. But I am . . . an expert in regulation."[90] And, indeed, Mr. Clark has extensive regulatory expertise: in addition to a Master of Science in Regulatory Science: Drug Development and Regulation, Mr. Clark has published on regulatory topics, and advised dozens of branded and generic pharmaceutical companies on regulatory matters. Actelion claims—without citing anything—that "Mr. Clark also testified that he had never advised clients on bioequivalence testing for any drug covered by a REMS program."[91] Not true. Mr. Clark testified that advising clients with respect to clinical trials had been "a major part" of his consulting business, and that he has advised clients as to how to conduct bioequivalence trials, in particular, for roughly 10 different products; while he

[87] *Id.* at 64:22-65:3; *id* at 62:12–16 ("I consulted on how [restricted distribution] was going to work and what the FDA was looking for").

[88] *Id.* at 68:20–72:11.

[89] Ex. 3, Clark Rep. ¶ 5.

[90] Ex. 9, Clark Tr. at 80:12–18; 81:21–82:3 ("I'm an expert in regulations and pharmaceutical regulations. The REMS programs, I believe I have considerable expertise in that.").

[91] Br. 14.

could not recall whether any of them had involved REMS, he did not testify that none of them involved a REMS as Actelion wrongly claims.[92] Mr. Clark also provided regulatory consultation on five ANDAs in the 2008–2011 timeframe specifically, liaising directly with FDA on behalf of the ANDA filers.[93]

Actelion seems to suggest that "the ANDA approval process for a medication covered by a shared REMS program"[94] bears no similarity to the process for other ANDAs. In reality, except for the sole additional requirement that they obtain approval for a SREMS program, the FDA approval process for REMS and non-REMS ANDAs is exactly the same. Mr. Clark's decades of professional experience with the process for generic drug approval and commercialization is more than adequate for him to opine, based on his careful review of their regulatory history, when generics would have been able to obtain FDA approval and enter the market absent the samples blockade, including when the SREMS process would conclude.

3. Mr. Clark's opinions on generic approval timing are well supported.

Despite Actelion's claims, Mr. Clark did not simply "assume . . . that the time it took the generic companies to achieve an approvable ANDA" would have been the same absent Actelion's unlawful conduct[95] (although such an approach is inherently conservative). He conducted an independent analysis that led him to opine as much. First, at paragraphs 95 through 225 of his opening report, Mr. Clark analyzed the full chronology of events for each generic covered by his opinions—from the date the generic initiated efforts to secure samples through the date it ultimately entered the market. Next, he determined how long after ANDA filing each generic had

[92] Ex. 9, Clark Tr. at 41:17–47:4.

[93] *Id.* at 212:17–213:8.

[94] Br. 14.

[95] *Id.* at 14.

satisfied FDA approval requirements. He then analyzed at paragraphs 276 through 282 the SREMS process to determine the time it took for that process to complete and the factors affecting that timing.[96] Finally, at paragraphs 272 through 290, Mr. Clark explained his methodology for using these inputs to determine the "but for" entry dates for each generic that he analyzed.

Actelion's arguments that this analysis is unreliable each fail. Actelion argues it was improper for Mr. Clark to rely on the contemporaneous documents produced by generic companies seeking to develop generic Tracleer to ascertain the earliest known date they were trying (unsuccessfully) to source samples for development and testing of generic Tracleer.[97] Actelion's premise appears to be that, unless there is proof of a written purchase request directly from a generic company to Actelion, the samples blockade had no impact on these generics' ability to secure samples. But GEHA challenges the overall scheme of blocking access to samples—including Actelion's conduct in preventing every distributor and pharmacy from selling to generic companies—not just Actelion's own refusals to sell samples to generics directly. Moreover, it makes no sense to limit the causation analysis to the generic manufacturers' first known direct request to Actelion. Normally, generics purchase samples (including for REMS drugs) from distributors or pharmacies in a routine process.[98] A generic "would never want to go to the [brand] manufacturer. That would be *the last thing* . . . you would want to do."[99] And, as Actelion notes,

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[96] Mr. Clark also did not "ignore[] the fact that FDA was undergoing significant changes" as defendants claim (Br. 14); he thoroughly considered and addressed these speculative arguments of Actelion's expert Mr. Shimer. Ex. 10, 8/4/2023 Rebuttal Rep. of Todd Clark ("Clark Rebuttal Rep.") ¶¶ 101–16.

[97] Br. 16.

[98] Ex. 1, Muzzio Rep. ¶¶ 25–31; Ex. 2, Muzzio Tr. at 42:16-43:18; Ex. 11, 9/9/2022 Dep. of Karen Walker ("Walker Tr.") at 90:4-91:3.

[99] Ex. 11, Walker Tr. at 88:15–91:3 (emphasis added); *id.* ("What you would rather do is go out and buy from a wholesaler, distributor, or even the normal channels, and this is absolutely

[redacted] was (eventually) able to secure samples through a relationship with a research institution and file its ANDA without making a direct request to Actelion. By Actelion's logic, its scheme had no effect on [redacted] development timeline despite clear evidence that, in fact, [redacted] *spent over three years in search of samples* before it was able to acquire a sufficient quantity for BE testing.[100]

Actelion also mischaracterizes those initial efforts of generic companies to secure samples. Mr. Clark outlined these efforts in detail in his report:

- [redacted] first sought to purchase samples no later than September 2008;[101]
- [redacted] sought to purchase samples no later than July 2011;[102]
- [redacted] attempted to acquire samples no later than January 2011;[103]
- [redacted] began seeking to purchase samples no later than November 2009;[104]

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allowed. The generic companies have licenses from state pharmacy boards that authorize them to buy prescription drugs . . . ").

Generic manufacturers are loathe to disclose the existence of their prospective ANDA to the brand company any earlier than necessary for fear of brand interference with their development and approval process—concerns that the documents in this case prove were justified. Ex. 3, Clark Rep. ¶ 63, Ex. 10, Clark Rebuttal Rep. ¶ 10 n.3, citing Pl. Ex. 186, June 1, 2010, email from Actelion executive Bill Fairey [redacted].

[100] *E.g.,* Ex. 3, Clark Rep. ¶¶ 96-101 [redacted]

[101] Ex. 3, Clark Rep. ¶ 96; [redacted].

[102] Ex. 3, Clark Rep. ¶ 111.

[103] *Id.* ¶ 141.

[104] *Id.* ¶ 176; [redacted] *see also* Ex. 15, Zydus Answer and Counterclaims at PageID 1207–12 (further unsuccessful efforts to acquire samples in 2009 and 2010).

- [redacted] began seeking to purchase samples no later than August 2011.[105]

Mr. Clark detailed the documents and deposition testimony he relied upon for his analysis and the experience and knowledge he brings to bear in evaluating those documents. That is exactly what an expert is supposed to do.

Further, Actelion's challenge to Mr. Clark's reliance on Ms. Muzzio's opinion[106] fails for the same reasons as noted above with respect to Ms. Muzzio: her expert opinion as to the timing of Tracleer samples purchases absent Actelion's blockade, and that generics could have purchased samples through the normal channels, is well-grounded in her decades of experience and the proper antitrust legal framework. *Supra* § I.A.[107]

Actelion also argues that Mr. Clark's analysis regarding the timing for approval of the SREMS aspect of the generic approval process is "pure speculation."[108] Again, Actelion is wrong. As Mr. Clark explains, generics can only enter the market after (1) conclusion of the SREMS process, and (2) ANDA approval.[109] He conducted a thorough, generic-by-generic analysis regarding when these events would occur absent the samples blockade. As Actelion admits,[110] Mr. Clark's opinion is supported by the testimony of four different fact witnesses in this case—*three separate and independent* non-party generic manufacturers directly involved in the SREMS process, plus the neutral SREMS manager, Syneos, hired by Actelion and the generics to manage

[105] Ex. 3, Clark Rep. ¶ 198.

[106] Br. 16-17.

[107] *See also FTC v. Shkreli*, 581 F. Supp. 3d 579, 596 (S.D.N.Y. 2022) ("Obtaining sufficient quantities of [brand samples] usually takes only a few days or, at most, a month.").

[108] Br. 19–21.

[109] Ex. 3, Clark Rep. ¶ 276.

[110] Br. 20.

the SREMS process.[111] [redacted] Because Mr. Clark demonstrates that without the samples blockade, the Tracleer SREMS process (which is triggered by the first bosentan ANDA filing) would have concluded before 2018 in light of earlier ANDA filings, the process would have pre-dated both the 2018 slowdown and a separate setback caused by the 2018 approval of the new Tracleer 32 mg dosage.[113] It is almost axiomatic that a SREMS process concluding prior to both of these events would take a shorter time than one that encountered them. However, Mr. Clark *also* identified the generic entry dates that would result under the more conservative scenarios in which the duration of the SREMS process was shortened by only six months, or was unchanged.[114] His model is therefore flexible and indeed can accommodate "any shared REMS approval date,"[115] which reinforces the conclusion that his testimony regarding SREMS and generic entry timing will help the jury in resolving that disputed issue.

Mr. Clark also conducted his own review of documents relating to the SREMS to verify the testimony of these fact witnesses and Actelion's contemporaneous internal documents.[116] And

[111] Ex. 3, Clark Rep. ¶¶ 278–81.

[112] Ex. 16, 10/18/2022 Dep. of Lindsay Crampton at 27:17–28:11; 148:12–149:4; 162:18–163:16 cited at Ex. 3, Clark Rep. ¶¶ 279–80 & nn.408–10.

[113] Ex. 3, Clark Rep. ¶¶ 277–82, 288. Even Actelion, a participant in the shared REMS process, was, as of June 2017, expecting a "jailbreak" of up to 11 generics entering the market around December 1, 2017 (14 months earlier than they actually did), but believed [redacted]. *Id.* ¶ 231 n.325, citing ACTLN01369913.

[114] Ex. 3, Clark Rep. ¶ 287–90.

[115] *Id.*

[116] Ex. 9, Clark Tr. at 174:4–177:4.

in response to Mr. Shimer's vague assertions that are untethered from any verifiable evidence,[117] Mr. Clark further bolstered his opinion with "an empirical analysis of FDA performance over the relevant period."[118] His opinions are well supported.

C. All of Mr. Clark's opinions were disclosed in compliance with Rule 26.

1. Mr. Clark's challenged opinions were adequately disclosed in his reports.

In addition to its Rule 702 and *Daubert* challenges, Actelion seeks to preclude Mr. Clark from offering any opinion on "what was permitted by the Tracleer REMS program," falsely claiming that "nowhere in either report does Mr. Clark disclose this opinion or any analysis supporting it."[119] But Mr. Clark's opening report discloses these opinions and his extensive supporting analysis,[120] and his rebuttal report does so even more explicitly: "selling samples of Tracleer to the generic companies would not require an 'exception' to the REMS, because *the Tracleer REMS did not prohibit selling samples to the generic companies*" and in his summary of opinions: "REMS did not prevent those sales [of Tracleer samples to generic companies] in the first instance."[121]

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[117] The language at page 20 of Actelion's own brief highlights their hypocrisy: Mr. Shimer's review "indicates a potential FDA focus on targeting shared REMS for marketed products," citing Mr. Shimer's Report ¶ 55. This is pure speculation.

[118] Ex. 10, Clark Rebuttal Rep. ¶¶ 101–16.

[119] Br. 10.

[120] Ex. 3, Clark Rep. ¶ 27 (generic manufacturers may lawfully obtain test samples with licenses and FDA/DEA registration); ¶ 26 (IRB oversight ensures safety of subjects in BE trials); ¶¶ 35–39, **78** ("FDA does not require submission of [BE] protocols and had already published [guidance] instructing generic sponsors to, among other things, follow all relevant aspect of the Tracleer REMS"); ¶ 116 (Roxane alleged Actelion's REMS claim was pretextual); ¶ 182 (same from Zydus); ¶ 273 ("generic companies would have been able to obtain U.S. RLD samples within the ordinary amount of time after seeking them, rather than being delayed").

[121] Ex. 10, Clark Rebuttal Rep. ¶¶ 8 & 57 (emphasis added); *see also* ¶¶ 9-10, 14–32 ("None of the official statements or publications from government agencies endorse the use of REMS programs to prevent generic access for safety or any other reason"), 46 , 49, 54, 56 ("[S]upplying

While counsel urged at his deposition that these were "new" opinions, Mr. Clark was clear throughout that he was simply restating opinions offered in his report.[122] Actelion cannot credibly claim surprise at trial when Mr. Clark clearly *articulated* this opinion at his deposition and throughout his reports. As cited above, a large portion of both of Mr. Clark's reports are squarely directed to the question of whether the Tracleer REMS prohibited sale of samples to generic companies for product development and BE testing.

2. Even if they had not been disclosed in his reports, disclosure in Mr. Clark's deposition complies with Fed. R. Civ. P. 26(a)(2)(c).

Actelion's motion should be denied for the independent reason that disclosure of an opinion from an expert during their deposition complies with Rule 26(a)(2)(c) of the Federal Rules of Civil Procedure. A 1993 note from the Rules' Advisory Committee makes this clear:

> The obligation to supplement disclosures and discoveryresponses applies whenever a party learns that its prior disclosures or responses are in some material respect incomplete or incorrect. **There is, however, no obligation to provide supplemental or corrective information that has been otherwise made known** to the parties in writing or during the discovery process, as when a witness not previously disclosed is identified **during the taking of a deposition** or when an expert during a deposition corrects information contained in an earlier report.[123]

The requirements of Rule 26(a)(2)(c) ensure that opposing parties are not surprised by new and/or contradictory opinions from an expert *at trial*.[124] Rule 26(e) requires a party to supplement an expert report when a "party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been

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samples would not have exposed Actelion to regulatory or legal risk."), 58–70 ([redacted] obtained samples without Actelion's knowledge and "the agency does not appear to have raised any concerns"), 71–77 (no case of FDA enforcement related to brands selling samples to generics).

[122] *See, e.g.,* Ex. 9, Clark Tr. at 98:6–99:5; 106:2–107:5.

[123] *See DR Distribs., LLC v. 21 Century Smoking, Inc*., 2016 WL 4077107, at *3–4 (N.D. Ill. Aug. 1, 2016) (emphasis added).

[124] *See* Fed. R. Civ. P. 26, Notes of the Advisory Comm. on Rules—1970 Amend.

made known to the other parties during the discovery process." As Actelion acknowledges, it understood Mr. Clark's opinion regarding obtaining samples under the REMS program as of his deposition, which occurred prior to the expert discovery deadline. Even if this opinion were new (and it was not, under any reasonable reading of Mr. Clark's reports), Actelion cannot argue that the opinion has "not otherwise been made known to the other parties during the discovery process."

Campbell v. U.S., the lone case on which Actelion relies is inapposite.[125] There, the court excluded an expert whose report: (1) was comprised of a one-page letter containing a conclusory opinion; (2) admittedly fell short of Fed. R. Civ. P. 26(a)(2)(C) requirements in multiple other respects; and (3) gave no indication it was intended to serve as an expert report until after the expert disclosure deadline has passed. Here, Mr. Clark offered a 133-page (with exhibits) opening report and an 83-page rebuttal report, both of which extensively addressed whether the Tracleer REMS prevented generic manufacturers from purchasing samples. It is unsurprising there is no caselaw supporting Actelion's position; Actelion turns the typical fact pattern on its head, asking this Court to require Mr. Clark to testify *differently* at trial than he did during his deposition.[126]

As detailed above, Mr. Clark "made known" his opinion through his reports and further explained those opinions when asked to do so at his deposition. GEHA did not "learn[] that in some material respect the disclosure or response is incomplete or incorrect" at any time. Actelion may have failed to understand an opinion offered by Mr. Clark in his reports, but gaining clarity on that is the purpose of expert depositions. There is no duty to supplement a report where another

[125] 2011 WL 588344, at *3, *6–8 (E.D. Va. 2011).

[126] For example, the case that Actelion cites for the applicable legal standard excluded an expert opinion disclosed for the first time *during trial* but allowed him "to testify regarding opinions he had expressed during his deposition." *S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 594 (4th Cir. 2003).

party misunderstands it, especially when that party has ample opportunity to ask clarifying questions at the expert's deposition and does precisely that.[127]

IV. CONCLUSION

For the foregoing reasons, Actelion's motion to exclude the testimony of Todd Clark and Daisy Rivera-Muzzio should be denied.

Dated: March 21, 2024

Respectfully submitted,

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[127] Notably, Actelion did not seek to reopen Mr. Clark's deposition to examine him on his "new" opinion. This is unsurprising given that defense counsel spent hours of Mr. Clark's deposition (which still concluded with time to spare) probing the exact opinions they now seek to exclude. This belies any suggestion that they did not have an adequate opportunity to cross-examine Mr. Clark on his opinions before trial.

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on March 21, 2024.

Dated: March 21, 2024

/s/ Sharon K. Robertson
Sharon K. Robertson